IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DISTRICT

MERIX PHARMACEUTICAL CORPORATION,	)	
Plaintiff,	)	
v.	)	No. 09 C 5871
EMS ACQUISITION CORPORATION,	)	Judge David H. Coar
Defendant.	)	Magistrate Judge Arlander Keys

THIRD AMENDED COMPLAINT FOR BREACHES OF CONFIDENTIAL DISCLOSURE AGREEMENT, BREACHES OF CONTRACTS, BREACH OF IMPLIED WARRANTY, NEGLIGENCE AND PROPERTY DAMAGE FROM CLINICAL TESTING OF PRODUCTS

Plaintiff, Merix Pharmaceutical Corporation, by its attorneys, files this Complaint against EMS Acquisition Corporation, and alleges as follows:

The Parties, Jurisdiction, and Venue

1. Merix Pharmaceutical Corporation ("Merix") is a corporation organized and existing under the laws of Illinois, with its principle place of business located at 18 E. Dundee Rd. Building 5, Suite 204, Barrington, IL 60010.

2. Upon information and belief, EMS Acquisition Corporation ("EMS") is a Pennsylvania corporation having its principal place of business at 1560 Industry Rd., Hatfield, Pennsylvania 19440.

3. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 because the parties are citizens of different States and/or countries and the amount in controversy exceeds the sum of $75,000, exclusive of interests and costs.

4. This Court has personal jurisdiction over all parties for the following reasons: (a) the ongoing confidential business relationship between the parties, out of which the claims herein arise, was entered into and centered within this District; (b) the contracts under which the parties operated for years, and which are at issue herein, were all entered into in this District; (c) the written contracts under which the parties operated for years, and which are at issue herein, specifically provide that the parties submit to the jurisdiction and venue of the courts of the State of Illinois, Cook County, within this District; (d) performance of services and goods under the contracts at issue herein was to be made, and was made, in substantial part within this District; (e) EMS' acts within this District, and out of which the claims herein arise, constitute breaches within this District of the contracts at issue herein; (f) EMS regularly does and solicits business, and derives substantial revenue from goods used or consumed, in the State of Illinois and within this District; (g) the tortuous acts of EMS, complained of herein, caused injury to person or property within the State of Illinois and this District; and (h) EMS expected or should have reasonably expected its tortuous acts to have consequences within the State of Illinois and this District.

5. Venue is proper in this judicial District under 28 U.S.C. §§1391(a) and (c) because EMS is subject to personal jurisdiction in this District, and a substantial part of the events giving rise to the claims stated, as well as damages resulting therefrom, occurred in this District.

COUNT I

BREACHES OF CONFIDENTIAL DISCLOSURE AGREEMENT

6. Merix is a pharmaceutical corporation and supplier of pharmaceutical products such as Releev which is an over-the-counter topical formulation targeting infections caused by the herpes virus. Releev relieves pain associated with herpes outbreaks and resolves symptoms of an outbreak most often in less than 24 hours.

7. Merix was locally founded in 1998 by Meryl Squires. From her facility in suburban Chicago, Ms. Squires grew her business into one of the most progressive and recognized pharmaceutical corporations in Illinois.

8. Releev is widely recognized as one of the premier medicines to effectively relieve pain and other symptoms associated with cold sores.

9. EMS is a cGMP FDA Registered Manufacturing Facility and was, during the periods in question herein, the manufacturer of pharmaceutical product for Merix, including the product Releev.

10. In or about 2003, Merix and EMS entered into a Confidential Disclosure Agreement ("CDA") under which all of the parties' future business operations and transactions were controlled and subjected to the overriding terms thereof.

11. The CDA provides, in pertinent part, that EMS "shall not use …, nor allow any of its employees … to use, any of [Merix' formulas or other] information . . . without first making sure that appropriate documentation of such permitted use … under this Agreement has been executed."

12. Subject to the terms of the CDA, as later further supplemented by the parties, Merix authorized EMS to use Merix' confidential information to produce two formulations for a double-blind clinical trial that included 200 vials each of the Releev formulation and of an *inert* placebo *that did not contain the active ingredients within the Releev formulation*. EMS was further specifically informed that its authorization to use Merix' confidential information was contingent upon EMS excluding from the placebo the listed active ingredient benzalkonium chloride ("BKC") and further ensuring that the placebo was inert.

13. The CDA was supplemented in writings between Merix and EMS via a series of e-mails sent between Merix and/or its counsel or agents, on the one hand, and EMS on the other.

14. EMS had knowledge that the primary purpose of performing the double-blind clinical trial was to produce evidence beneficial to Merix in the then pending litigation to which Merix was a party.

15. On or about October 3, 2005, EMS produced the Placebo but included BKC in the formulation, contrary to specific instructions from Merix and the PRACS Institute ("PRACS") to omit BKC, and which EMS bottled and sent to PRACS to conduct the double blind study.

16. Merix had no knowledge of the inclusion of BKC into the Placebo formulation because, by the very nature of a clinical trial, Merix was required to be blinded for the entirety of the clinical trial. EMS had knowledge that Merix was required to be blinded.

17. The CDA was and remains a valid and enforceable contract and Merix has met its obligations under the terms of the CDA.

18. The use, by EMS and its employees, of Merix' confidential information to produce two formulations which did *not* exclude BKC from the placebo and which placebo was *not* inert constituted an unauthorized use of Merix' confidential information in breach of the CDA.

19. As a result, Merix was forced to run a second double blind clinical trial with product manufactured by a separate manufacturer and incur further legal expenses in its ongoing litigation while conducting the second clinical trial all to the substantial injury of Merix.

20. Separate and apart from the unauthorized *use*, by EMS, of Merix' confidential information and formulas complained of above, EMS has also blatantly breached the provisions of the CDA which prohibit unauthorized *disclosure* of Merix' confidential information and formulas. In attempting to avoid being held responsible for the acts complained of herein, EMS further breached the terms of the CDA by filing herein, and thereby disclosing to the general public, Exhibit 1 and Exhibit 8 to EMS' each of two different motions to dismiss or transfer, both

of which Exhibits include a complete and detailed disclosure of Merix' highly-confidential product formula along with step-by-step instructions for manufacturing the product and the details of confidential methods and parameters relating thereto. Those recent public disclosures by EMS, in blatant breach of the CDA, have caused substantial injury to Merix for which Merix will seek damages herein, and further are the subject of a separate emergency motion to be filed herein by Merix which will ask this Court to Order that the clerk remove both sets of said Exhibit 1 and Exhibit 8 from the public record herein and, instead, place those documents under seal, all in an effort to mitigate, if possible, Merix' further damages from the said unauthorized disclosures.

COUNT II

BREACH OF WRITTEN CONTRACT

21. Merix repeats and realleges paragraphs 1-20 as if fully stated in this paragraph 21.

22. In or about 2005, Merix and EMS entered into a global operating agreement ("the Agreement") which further memorialized the parties' prior years of operating practices.

23. In or about 2005, pursuant to the Agreement, Merix placed an order wherein EMS was to produce two formulations for a double-blind clinical trial that included 200 vials of the Releev formulation, and 200 vials of a placebo that all parties were informed had to exclude the listed active ingredient benzalkonium chloride ("BKC") and which was to be otherwise inert.

24. The Agreement was supplemented in writings between Merix and EMS via a series of emails sent between Merix and/or its counsel or agents, on the one hand, and EMS on the other.

25. EMS had knowledge that the primary purpose of performing the double-blind clinical trial was to produce evidence beneficial to Merix in the then pending litigation to which Merix was a party.

26. On or about October 3, 2005, EMS produced the Placebo but included BKC in the formulation, contrary to specific instructions from Merix and the PRACS Institute ("PRACS") to omit BKC, and which EMS bottled and sent to PRACS to conduct the double blind study.

27. Merix had no knowledge of the inclusion of BKC into the Placebo formulation because by the very nature of a clinical trial, Merix was required to be blinded for the entirety of the clinical trial. EMS had knowledge that Merix was required to be blinded.

28. The Agreement was and remains a valid and enforceable contract and Merix has met its obligations under the terms of the Agreement.

29. The inclusion of BKC in the placebo was a breach of the Agreement.

30. As a result, Merix was forced to run a second double blind clinical trial with product manufactured by a separate manufacturer and incur further legal expenses in its ongoing litigation while conducting the second clinical trial all to the substantial injury of Merix.

COUNT III

BREACH OF ORAL CONTRACT

31. Merix repeats and realleges paragraphs 1-30 as if fully stated in this paragraph 31.

32. In or around 2005, Merix and EMS entered into a contract ("the Oral Agreement") wherein EMS was to manufacture Releev and a placebo for a double-blind clinical trial to be done for the benefit of Merix.

33. The Oral Agreement obligated, *inter alia*, EMS to manufacture Releev in one batch containing the normal formula for Releev and another batch (the placebo) excluding the listed active ingredient BKC and which was also to be otherwise inert.

34. EMS had knowledge that the primary purpose of performing a clinical trial was to produce evidence favorable to Merix for use in the pending litigation to which Merix was a party.

35. On or around October 3, 2005, EMS produced the Placebo but included BKC in the formulation, contrary to instructions from Merix and the PRACS Institute ("PRACS") to omit BKC, and which was bottled and then sent to the randomization house for ultimate use by PRACS in conducting the double blind study.

36. Merix had no knowledge of the inclusion of BKC into the Placebo formulation because by the very nature of a double-blind clinical trial, Merix was required to be blinded for the entirety of the clinical trial. EMS had knowledge that Merix was required to be blinded.

37. The Oral Agreement was and remains a valid and enforceable contract and Merix has met its obligations under the terms of the Oral Agreement.

38. The inclusion of BKC in the placebo was a breach of the Oral Agreement.

39. As a result, Merix was forced to run a second double blind clinical trial with product manufactured by a separate manufacturer and incur further legal expenses in its ongoing litigation while conducting the second clinical trial all to the substantial injury of Merix.

COUNT IV

BREACH OF IMPLIED WARRANTY

40. Merix repeats and realleges paragraphs 1-39 as if fully stated in this paragraph 40.

41. EMS manufactured and sold to Merix two formulations for a clinical trial that was to include 200 vials of the normal Releev formulation, and 200 vials of a placebo that was to be inert and that specifically excluded the listed active ingredient BKC.

42. EMS had knowledge that the two formulations would be used in a clinical trial wherein one formulation contained the standard Releev formula and another which was to be inert and that specifically excluded the listed active ingredient BKC.

43. Merix relied upon EMS's expertise and regulatory compliance as an FDA registered pharmaceutical manufacturer to produce two formulations wherein one formulation contained the standard Releev formula and another formulation which was to be inert and that specifically excluded the listed active ingredient BKC.

44. The two formulations which both contained the listed active ingredient BKC were not fit for use in a double blind clinical trial.

45. Merix was damaged by EMS's breach.

COUNT V

NEGLIGENCE

46. Merix repeats and realleges paragraphs 1-45 as if fully stated in this paragraph 46.

47. Irrespective of any contract between the parties, EMS, as a cGMP FDA Regulated Facility, owed all of its customers a commensurate duty of care in manufacturing products with appropriate attention to the attributes and ingredients thereof, and in particular while manufacturing two products for a clinical trial of the Merix' Releev formulation, including a placebo which was to be inert and specifically exclude the listed active ingredients.

48. EMS breached its duty of care and attention to detail by incorrectly manufacturing and distributing, for use in a clinical trial, a placebo which contained the listed active ingredient BKC and which was not inert.

49. As a result of EMS negligently including BKC in the placebos, great damage was done to the property (the placebos which Merix purchased, and the PRACS Report) both of which Merix paid great sums of money for, and which Merix needed for use in its pending litigation with GlaxoSmithKline, to the point of its complete destruction. Thus, Merix suffered great property damage arising from clinical testing of products negligently manufactured and distributed by EMS. Further, Merix was then forced to run a second double blind clinical trial

with product manufactured by a separate manufacturer and incur further legal expenses in its ongoing litigation while conducting the second clinical trial, all to the substantial injury and consequential damages of Merix.

50. EMS' negligent conduct has caused substantial property damages and further consequential injury to Merix, for which Merix seeks recovery.

COUNT VI

PROPERTY DAMAGES ARISING FROM CLINICAL TESTING OF PRODUCTS MANUFACTURED BY EMS IN BREACH OF REPRESENTATIONS OF QUALITY AND WARRANTIES OF FITNESS FOR PARTICULAR PURPOSE

51. Merix repeats and realleges paragraphs 1-50 as if fully stated in this paragraph 51.

52. Irrespective of any contracts entered into between the parties, EMS represented to Merix that it was experienced and skilled in the manufacture of products and placebos for use in clinical trials. EMS further represented and warranted to Merix that it could and would manufacture two different products of precise quality and which would be particularly well suited for use in a clinical trial, that the two products would include 200 vials of the normal Releev formulation, and 200 vials of a placebo that would exclude the listed active ingredients and would be inert.

53. EMS had full knowledge that the two different products it manufactured and distributed to Merix would be used in a double-blind clinical trial to produce a formal final report (the “PRACS Report”), that Merix would be paying large sums of money for that property, and which property would be highly valuable to Merix for use in its pending litigation with GlaxoSmithKline (“GSK”) .

54. In reliance upon EMS’ representations and warranties, Merix purchased the two different products that EMS manufactured, and proceeded to authorize their testing in the

double-blind clinical trial. In advance, Merix paid and obligated itself to pay, large sums of money to PRACS and others in order to produce and purchase the PRACS Report, which PRACS Report constitutes tangible property owned by Merix.

55. The product which EMS manufactured and distributed for use in the clinical trial as the placebo was, however, not inert and contained the listed active ingredient BKC, causing great damage to the placebos in breach of EMS' representations of quality and warranty of fitness for particular purpose referenced above. Due to Merix being blinded in the clinical trial, Merix did not discover the manufacturing defect until the clinical trial creating the PRACS Report was completed.

56. As a result of EMS including BKC in the placebos, great damage was done to the property (the placebos which Merix purchased, and the PRACS Report) both of which Merix paid great sums of money for, and which Merix needed for use in its pending litigation with GlaxoSmithKline, to the point of its complete destruction. Thus, Merix suffered great property damage arising out of clinical testing of products manufactured and distributed by EMS contrary to the representations of quality, and warranties of fitness, made by EMS. Further, Merix was then forced to run a second double blind clinical trial with product manufactured by a separate manufacturer and incur further legal expenses in its ongoing litigation while conducting the second clinical trial, all to the substantial injury and consequential damages of Merix.

57. Merix seeks recovery of the property damages it suffered due to the destruction of its property, and further consequential damages as referenced above.

PRAYER FOR RELIEF

WHEREFORE, Merix seeks judgment against the Defendant, and the following relief:

a. EMS be found liable for breaching the CDA between EMS and Merix and thus be ordered to account for and pay to Merix actual and consequential damages incurred that were caused by EMS' breaches;

b. EMS be found liable for breaching the Agreement between Merix and EMS and thus be ordered to account for and pay to Merix actual and consequential damages incurred that were caused by EMS' breach;

c. EMS be found liable for breaching the Oral Agreement between Merix and EMS and be ordered to account for and pay to Merix actual and consequential damages incurred that were caused by EMS' breach;

d. EMS be ordered to account for and pay to Merix damages incurred which were a result of EMS' unjust enrichment;

e. EMS be found liable for breach of implied warranty and be ordered to account for and pay to Merix actual and consequential damages incurred and caused by EMS' negligence;

f. EMS be found liable for its negligence for improperly manufacturing a placebo containing the listed active ingredient and thus be ordered to account for and pay to Merix actual and consequential damages incurred that were caused by EMS' negligence;

g. EMS be found liable for the property damages arising out of the clinical testing of products manufactured and distributed by EMS in breach of its representations of quality and warranties of fitness for particular purpose, and thus be ordered to account for and pay to Merix its resulting actual and consequential damages;

h. Merix be awarded its attorneys fees and costs incurred;

i. Merix be awarded prejudgment interest and other such further relief as the Court deems just and equitable.

RESPECTFULLY SUBMITTED,

/s/ Richard Kirk Cannon

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(847) 381-1600

Attorneys for Plaintiff Merix Pharmaceutical Corporation

JURY DEMAND

Plaintiff Merix Pharmaceuticals, Corporation hereby demands a trial by jury of any issue triable of right by a jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

RESPECTFULLY SUBMITTED,

/s/ Richard Kirk Cannon
Richard Kirk Cannon
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Barrington, IL 60010-4311
(847) 381-1600

Attorneys for Plaintiff Merix Pharmaceutical Corporation

CERTIFICATE OF SERVICE

I, Richard K. Cannon, caused to be served a copy of the foregoing:

THIRD AMENDED COMPLAINT FOR BREACHES OF CONFIDENTIAL DISCLOSURE AGREEMENT, BREACHES OF CONTRACTS, BREACH OF IMPLIED WARRANTY, NEGLIGENCE AND PROPERTY DAMAGE FROM CLINICAL TESTING OF PRODUCTS

by filing same with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following counsel of record:

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